

MERCHANT, GOULD, SMITH, EDELL, WELTER & SCHMIDT

United States Patent Application



COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors

are named below) of the s MONITORING DEVICE	ubject matter which is claimed and for AND METHODS OF USE	which a patent is sought or	n the invention entitled: ANALYTE
c. was filed on April 3	FE MONITORING DEVICE AND ME 0, 1998 as application serial no. 09/070 I claimed in international no. filed	ETHODS OF USE, having a 0,677 and was amended on and as amended on	an attorney docket number 12008.15US01 (if applicable) (in the case of a PCT-filed (if any), which I have reviewed and for which I
I hereby state that I have r any amendment referred to	eviewed and understand the contents on above.	f the above-identified spec	ification, including the claims, as amended by
I acknowledge the duty to of Federal Regulations, §	disclose information which is material 1.56 (attached hereto).	to the patentability of this	application in accordance with Title 37, Code
certificate listed below and	ority benefits under Title 35, United Sta d have also identified below any foreig the basis of which priority is claimed:	ates Code, § 119/365 of an napplication for patent or	y foreign application(s) for patent or inventor's inventor's certificate having a filing date before
a. ⊠ no such applications b. ☐ such applications ha			
	FOREIGN APPLICATION(S), IF ANY,	CLAIMING PRIORITY UND	ER 35 USC § 119
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
A	LL FOREIGN APPLICATION(S), IF ANY, I	FILED BEFORE THE PRIORI	TY APPLICATION(S)
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)

I hereby appoint the following attorney(s, d/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Albrecht, John W.	Reg. No. 40,481	Lacy, Paul E.	Dec 31- 20.046
Ansems, Gregory M.	Reg. No. P-42,264	Larson, James A.	Reg. No. 38,946
Batzli, Brian H.	Reg. No. 32,960	•	Reg. No. 40,443
Beard, John L.	Reg. No. 27,612	Lasky, Michael B.	Reg. No. 29,555
Berman, Charles	Reg. No. 29,249	Lindquist, Timothy A.	Reg. No. 40,701
Black, Bruce E.	•	Lynch, David W.	Reg. No. 36,204
Blasdell, Thomas L.	Reg. No. P-41,622	McDaniel, Karen D.	Reg. No. 37,674
	Reg. No. 31,329	McDonald, Daniel W.	Reg. No. 32,044
Bogucki, Raymond A.	Reg. No. 17,426	McIntyre, Iain A.	Reg. No. 40,337
Bruess, Steven C.	Reg. No. 34,130	Mueller, Douglas P.	Reg. No. 30,300
Byrne, Linda M.	Reg. No. 32,404	Nasiedlak, Tyler L.	Reg. No. 40,099
Canady, Karen S.	Reg. No. 39,927	Nelson, Albin J.	Reg. No. 28,650
Carlson, Alan G.	Reg. No. 25,959	Orler, Anthony J.	Reg. No. 41,232
Carter, Charles G.	Reg. No. 35,093	Pauly, Daniel M.	Reg. No. 40,123
Caspers, Philip P.	Reg. No. 33,227	Plunkett, Theodore	Reg. No. 37,209
Chiapetta, James R.	Reg. No. 39,634	Reich, John C.	Reg. No. 37,703
Clifford, John A.	Reg. No. 30,247	Reiland, Earl D.	Reg. No. 25,767
Daignault, Ronald A.	Reg. No. 25,968	Rittmaster, Ted R.	Reg. No. 32,933
Daley, Dennis R.	Reg. No. 34,994	Schmaltz, David G.	Reg. No. 39,828
Dalglish, Leslie E.	Reg. No. 40,579	Schuman, Mark D.	Reg. No. 31,197
Daulton, Julie R.	Reg. No. 36,414	Schumann, Michael D.	Reg. No. 30,422
DeVries Smith, Kate	Reg. No. P-42,157	Sebald, Gregory A.	Reg. No. 33,280
DiPietro, Mark J.	Reg. No. 28,707	Sharp, Janice A.	Reg. No. 34,051
Edell, Robert T.	Reg. No. 20,187	Skoog, Mark T.	Reg. No. 40,178
Epp Ryan, Sandra	Reg. No. 39,667	Smith, Jerome R.	Reg. No. 35,684
Farber, Michael B.	Reg. No. 32,612	Soderberg, Richard	Reg. NoP-43,352
Funk, Steven R.	Reg. No. 37,830	Sumner, John P.	Reg. No. 29,114
Glance, Robert J.	Reg. No. 40,620	Sumners, John S.	Reg. No. 24,216
Golla, Charles E.	Reg. No. 26,896	Tellekson, David K.	Reg. No. 32,314
Gorman, Alan G.	Reg. No. 38,472	Trembath, Jon R.	Reg. No. 38,344
Gould, John D.	Reg. No. 18,223	Underhill, Albert L.	Reg. No. 27,403
Gregson, Richard	Reg. No. P-41,804	Vandenburgh, J. Derek	Reg. No. 32,179
Gresens, John J.	Reg. No. 33,112	Victor, David W.	Reg. No. 39,867
Hamre, Curtis B.	Reg. No. 29,165	Welter, Paul A.	Reg. No. 20,890
Hillson, Randall A.	Reg. No. 31,838	Whipps, Brian	Reg. No. P-43,261
Johnston, Scott W.	Reg. No. 39,721	Williams, Douglas J.	Reg. No. 27,054
Kastelic, Joseph M.	Reg. No. 37,160	Witt McDonald, Jonelle	Reg. No. P-41,980
Kettelberger, Denise	Reg. No. 33,924	Wood, Gregory B.	Reg. No. 28,133
Komanduri, Janaki	Reg. No. 40,684	Wood, William J.	Reg. No. P-42,236
Kowalchyk, Alan W.	Reg. No. 31,535	Xu, Min S.	Reg. No. 39,536
Kowalchyk, Katherine M.	Reg. No. 36,848	,	105. 110. 37,330
•	3		

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant, Gould, Smith, Edell, Welter & Schmidt to the contrary.

Please direct all correspondence in this case to Merchant, Gould, Smith, Edell, Welter & Schmidt at the address indicated below:

Merchant, Gould, Smith, Edell,
Welter & Schmidt
3100 Norwest Center
90 South Seventh Street
Minneapolis, MN 55402-4131

I hereby declare that all statements made in ein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name	Family Name	First Given Name		Second Given Name
Of Inventor	SAY	JAMES		
Residence	City		,	Country of Citizenship
		CALIFORNIA		USA
		City		State & Zip Code/Country
	L	ALAMEDA		CALIFORNIA 94501/USA
iture of Inventor 2	01:		Date:	
Full Name	Family Name	First Given Name		Second Given Name
Of Inventor	TOMASCO	MICHAEL		F.
Residence	City	State or Foreign Country	,	Country of Citizenship
	CUPERTINO	CALIFORNIA		USA
Post Office	Post Office Address	City		State & Zip Code/Country
	4—	CUPERTINO		CALIFORNIA 95015/USA
iture of Inventor 2	02:		Date:	
Full Name	Family Name	First Given Name		Second Given Name
Of Inventor	HELLER	ADAM		
Residence	City	State or Foreign Country	<i>i</i>	Country of Citizenship
& Citizenship	AUSTIN	TEXAS		USA
Post Office	Post Office Address	City		State & Zip Code/Country
		AUSTIN		TEXAS 78731/USA
iture of Inventor 2	03:		Date:	
Full Name	Family Name	First Given Name		Second Given Name
Of Inventor	GAL	YORAM		
Residence	City	State or Foreign Country	7	Country of Citizenship
& Citizenship	KIBBUTZ YAGUR	ISRAEL		ISRAEL
Post Office	1 ost Office Address	City		State & Zip Code/Country
	·	KIBBUTZ YAGUR, 3006		ISRAEL
ature of Inventor 2	04: rall)	Date:	Z July 98
Full Name	Family Name	First Given Name		Second Given Name
Of Inventor	ARIA	BEHRAD		
Residence	City	State or Foreign Country	у	Country of Citizenship
& Citizenship	ALAMEDA	CALIFORNIA		USA
Post Office	Post Office Address	City		State & Zip Code/Country
Address	817 SANTA CLARA AVENUE	ALAMEDA		CALIFORNIA 94502/USA
ature of Inventor 2	.05:		Date:	
	Residence & Citizenship Post Office Address ature of Inventor 2 Full Name Of Inventor Residence & Citizenship Post Office Address ature of Inventor 2 Full Name Of Inventor Residence & Citizenship Post Office Address ature of Inventor 2 Full Name Of Inventor 2 Residence & Citizenship Post Office Address ature of Inventor 2 Full Name Of Inventor 2	Residence & City & Citizenship Post Office Address Ad0 COLA BALLENA #A sture of Inventor 201: Full Name Of Inventor Post Office & City & Citizenship Post Office Address Address City CUPERTINO Post Office Address	Of Inventor Residence & City & Citizenship ALAMEDA Post Office Address Adoress Adoress Adoress Ature of Inventor 201: Full Name Of Inventor Post Office Address City Address Active of Inventor City Address City ALAMEDA Family Name Of Inventor City Address City Address City Address City Address City Address City Address City CUPERTINO CALIFORNIA Post Office Address City Address City Address City CUPERTINO State or Foreign Country CUPERTINO CUPERTINO CUPERTINO State or Foreign Country City Address City Address City Address City Address City Austin Fundame Of Inventor 203: Full Name Of Inventor GAL Family Name Of Inventor GAL First Given Name YORAM First Given Name YORAM First Given Name YORAM First Given Name YORAM Fost Office Address City Kibbutz YAGUR, 3006 State or Foreign Country City City Address AlaMEDA First Given Name BEHRAD First Given Name BEHRAD First Given Name BEHRAD CALIFORNIA CALIFORNIA	Of Inventor SAY JAMES Residence & City & Citizenship ALAMEDA CALIFORNIA CALIFORNIA Post Office Post Office Address 460 COLA BALLENA #A ALAMEDA City ALAMEDA Address 460 COLA BALLENA #A ALAMEDA ALAMEDA Full Name Of Inventor 201: Family Name MICHAEL Full Name Of Inventor TOMASCO First Given Name MICHAEL Residence & City & State or Foreign Country CALIFORNIA COLIPERTINO Post Office Address 2253 POPPY DRIVE CUPERTINO Address 2253 POPPY DRIVE CUPERTINO Alume of Inventor 202: Date: Full Name Of Inventor #IELLER First Given Name ADAM Residence & City & State or Foreign Country TEXAS City AUSTIN Austrin Austrin First Given Name York Office Address 317 VALBURN CIRCLE City AUSTIN Auture of Inventor 203: Date: Full Name Of Inventor GAL First Given Name YORAM Residence & City & KIBBUTZ YAGUR State or Foreign Country ISRAEL Post Office Post Office Address Post O

2 0 6 Signa	Full Name Of Inventor Residence & Citizenship	Family Name HELLER	First Given Name EPHRAIM		Second Given Name
6	Residence	·	EPHRAIM		
6					
$oldsymbol{\bot}$	& Citizenshin	City	State or Foreign Country		Country of Citizenship
$oldsymbol{\bot}$	& Citizenship	OAKLAND	CALIFORNIA		USA
Signa	Post Office	Post Office Address	City		State & Zip Code/Country
Signa	Address	8101 SKYLINE BOULEVARD	OAKLAND	_	CALIFORNIA 94611/USA
	ture of Inventor 20	06:		Date:	
	Full Name	Family Name	First Given Name	L	Second Given Name
2	Of Inventor	PLANTE	PHILLIP		JOHN
0	Residence	City	State or Foreign Country		Country of Citizenship
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7	Post Office	Post Office Address	City		State & Zip Code/Country
	Address	M-116, 655 SOUTH FAIR OAKS AVENUE	SUNNYVALE	T	CALIFORNIA 94086/USA
Signa	ture of Inventor 20	07:		Date:	
	Full Name	Family Name	First Given Name		Second Given Name
2	Of Inventor	VREEKE	MARK		S.
0	Residence	City	State or Foreign Country		Country of Citizenship
ļ	& Citizenship	ALAMEDA	CALIFORNIA		USA
8:	Post Office	Post Office Address	City		State & Zip Code/Country
	Address	2826 CALHOUN STREET	ALAMEDA		CALIFORNIA 94501/USA
Signa	ture of Inventor 20	08:		Date:	
T	Full Name	Family Name	First Given Name	I	Second Given Name
2	Of Inventor	FRIEDMAN	KEITH		A.
0	Residence	City	State or Foreign Country	 	Country of Citizenship
Ļ	& Citizenship	AUSTIN	TEXAS		USA
9	Post Office	Post Office Address	City		State & Zip Code/Country
L	Address	500 E. RIVERSIDE DRIVE, APT. 230	AUSTIN		TEXAS 78704/USA
Signa	ture of Inventor 20	09:		Date:	
	Full Name	Family Name	First Given Name	I	Second Given Name
2	Of Inventor	COLMAN	FREDRIC		c.
1	Residence	City	State or Foreign Country		Country of Citizenship
ļ	& Citizenship	BERKELEY	CALIFORNIA		USA
0	Post Office	Post Office Address	City		State & Zip Code/Country
	Address	6879 BRISTOL DRIVE	BERKELEY		CALIFORNIA 94705/USA
Signa	ture of Inventor 2	10:	_	Date:	

- (a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
 - (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
 - (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;

or

- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

- (c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:
 - (1) Each inventor named in the application:
 - (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

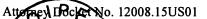
SMALL BUSINESS

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN	
I here that I am a) the owner of the small business concern identified below:	
b) an official of the small business concern empowered to act on behalf of the concern identified below:	
NAME OF CONCERN: E. Heller & Company ADDRESS OF CONCERN: 1311 Harbor Bay Parkway, Suite 1000 Alameda, California 94502	
I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.801-805, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.	
I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled PROCESS FOR PRODUCING AN ELECTROCHEMICAL BIOSENSOR by inventor(s) James Say, Michael F. Tomasco, Adam Heller, Yoram Gal, Behrad Aria, Ephraim Heller, Phillip John Plante and Mark S. Vreeke, described in	
a) ☐ the specification filed herewith. b) ☐ provisional application serial no, filed c) ☒ non-provisional application serial no. 09/070,677, filed April 30, 1998. d) ☐ patent no, issued	
If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)	
NAME: TheraSense LLC	
ADDRESS: 1311 Harbor Bay Parkway, Suite 1000, Alameda, CA 94502 a) ☐ INDIVIDUAL b) ☑ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION	
NAME:	
ADDRESS: a) INDIVIDUAL b) SMALL BUSINESS CONCERN c) NONPROFIT ORGANIZATION	
I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b))	l
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.	
NAME: Ephraim Heller	
TITLE: President ADDRESS: 1311 Harbor Bay Parkway, Suite 1000, Alameda, California 94502	
SIGNATURE: Eal Will Date: 6/22/98	
Date. W/ OK//A	

I

SMALL BUSINESS

FERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. 1.9(f) AND 1.27(c)) - SMALL BUSINESS CONCERN I hereby de lane (1) am
 a) the owner of the small business concern identified below: b) an official of the small business concern empowered to act on behalf of the concern identified below:
NAME OF CONCERN: TheraSense LLC ADDRESS OF CONCERN: 1311 Harbor Bay Parkway, Suite 1000 Alameda, California 94502
I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.801-805, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.
I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled PROCESS FOR PRODUCING AN ELECTROCHEMICAL BIOSENSOR by inventor(s) James Say, Michael F. Tomasco, Adam Heller, Yoram Gal, Behrad Aria, Ephraim Heller, Phillip John Plante and Mark S. Vreeke, described in
a) ☐ the specification filed herewith. b) ☐ provisional application serial no, filed c) ☒ non-provisional application serial no. 09/070,677, filed April 30, 1998. d) ☐ patent no, issued
If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. 1.27)
NAME: E. Heller & Company ADDRESS: 1311 Harbor Bay Parkway, Suite 1000, Alameda, CA 94502
a) ☐ INDIVIDUAL b) ☑ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION
NAME: ADDRESS:
a) INDIVIDUAL b) SMALL BUSINESS CONCERN c) NONPROFIT ORGANIZATION
I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.28(b))
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.
NAME: Ephraim Heller
ADDRESS: Vice President ADDRESS: 1311 Harbor Bay Parkway, Suite 1000, Alameda, California 94502
SIGNATURE: Esl Hell Date: 6/22/98





MERCHANT, GOULD, SMITH, EDELL, WELTER & SCHMIDT United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: ANALYTE MONITORING DEVICE AND METHODS OF USE

- a. | is attached hereto
- b.

 is entitled ANALYTE MONITORING DEVICE AND METHODS OF USE, having an attorney docket number 12008.15US01
- c. was filed on April 30, 1998 as application serial no. 09/070,677 and was amended on (if applicable) (in the case of a PCT-filed application) described and claimed in international no. filed and as amended on (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (attached hereto).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

- a. \(\omega\) no such applications have been filed.
- b. such applications have been filed as follows:

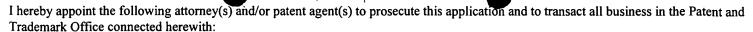
	FOREIGN APPLICATION(S), IF ANY	, CLAIMING PRIORITY UNDER	35 USC § 119		
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)		
	ALL FOREIGN APPLICATION(S), IF ANY,	FILED BEFORE THE PRIORITY	APPLICATION(S)		
COUNTRY APPLICATION NUMBER DATE OF FILING (day, month, year) DATE OF ISSUE (day, month, year)					

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)
	·



Albrecht, John W.	Reg. No. 40,481	Lacy, Paul E.	Reg. No. 38,946
Ansems, Gregory M.	Reg. No. P-42,264	Larson, James A.	Reg. No. 40,443
Batzli, Brian H.	Reg. No. 32,960	Lasky, Michael B.	Reg. No. 29,555
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Berman, Charles	Reg. No. 29,249	Lynch, David W.	Reg. No. 36,204
Black, Bruce E.	Reg. No. P-41,622	McDaniel, Karen D.	Reg. No. 37,674
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Bruess, Steven C.	Reg. No. 34,130	Mueller, Douglas P.	Reg. No. 30,300
Byrne, Linda M.	Reg. No. 32,404	Nasiedlak, Tyler L.	Reg. No. 40,099
Canady, Karen S.	Reg. No. 39,927	Nelson, Albin J.	Reg. No. 28,650
Carlson, Alan G.	Reg. No. 25,959	Orler, Anthony J.	Reg. No. 41,232
Carter, Charles G.	Reg. No. 35,093	Pauly, Daniel M.	Reg. No. 40,123
Caspers, Philip P.	Reg. No. 33,227	Plunkett, Theodore	Reg. No. 37,209
Chiapetta, James R.	Reg. No. 39,634	Reich, John C.	Reg. No. 37,703
Clifford, John A.	Reg. No. 30,247	Reiland, Earl D.	Reg. No. 25,767
Daignault, Ronald A.	Reg. No. 25,968	Rittmaster, Ted R.	Reg. No. 32,933
Daley, Dennis R.	Reg. No. 34,994	Schmaltz, David G.	Reg. No. 39,828
Dalglish, Leslie E.	Reg. No. 40,579	Schuman, Mark D.	Reg. No. 31,197
Daulton, Julie R.	Reg. No. 36,414	Schumann, Michael D.	Reg. No. 30,422
DeVries Smith, Kate	Reg. No. P-42,157	Sebald, Gregory A.	Reg. No. 33,280
DiPietro, Mark J.	Reg. No. 28,707	Sharp, Janice A.	Reg. No. 34,051
Edell, Robert T.	Reg. No. 20,187	Skoog, Mark T.	Reg. No. 40,178
Epp Ryan, Sandra	Reg. No. 39,667	Smith, Jerome R.	Reg. No. 35,684
Farber, Michael B.	Reg. No. 32,612	Soderberg, Richard	Reg. NoP-43,352
Funk, Steven R.	Reg. No. 37,830	Sumner, John P.	Reg. No. 29,114
Glance, Robert J.	Reg. No. 40,620	Sumners, John S.	Reg. No. 24,216
Golla, Charles E.	Reg. No. 26,896	Tellekson, David K.	Reg. No. 32,314
Gorman, Alan G.	Reg. No. 38,472	Trembath, Jon R.	Reg. No. 38,344
Gould, John D.	Reg. No. 18,223	Underhill, Albert L.	Reg. No. 27,403
Gregson, Richard	Reg. No. P-41,804	Vandenburgh, J. Derek	Reg. No. 32,179
Gresens, John J.	Reg. No. 33,112	Victor, David W.	Reg. No. 39,867
Hamre, Curtis B.	Reg. No. 29,165	Welter, Paul A.	Reg. No. 20,890
Hillson, Randall A.	Reg. No. 31,838	Whipps, Brian	Reg. No. P-43,261
Johnston, Scott W.	Reg. No. 39,721	Williams, Douglas J.	Reg. No. 27,054
Kastelic, Joseph M.	Reg. No. 37,160	Witt McDonald, Jonelle	Reg. No. P-41,980
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I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant, Gould, Smith, Edell, Welter & Schmidt to the contrary.

Please direct all correspondence in this case to Merchant, Gould, Smith, Edell, Welter & Schmidt at the address indicated below:

Merchant, Gould, Smith, Edell, Welter & Schmidt 3100 Norwest Center 90 South Seventh Street Minneapolis, MN 55402-4131 I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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§ 1.56 Duty to disclose information make ial to patentability.

- (a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
 - (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
 - (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;

or

- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

- (c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:
 - (1) Each inventor named in the application:
 - (2) Each attorney or agent who prepares or prosecutes the application; and
- Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.